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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,630	11/28/2001	Kimberly A. Gillis	102729-10 (AM 100491)	3476

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/996,630	Gillis
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 11, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above, claim(s) *23-50* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-22* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *0803*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, corresponding to claims 1-22, in Paper No. 0803 is acknowledged. The traversal is on the ground(s) that a single search should suffice for examination of all aspects of this invention because all groups are directed to prostate cancer and KIAA . This is not found persuasive because as made clear in the last office action of restriction requirement that Groups II, III and IV belong to class and subclass different from Group I . A proper field of search normally includes the subclass in which the claimed subject matter of an application would be properly classified. Moreover, the traditional method of browsing all patent documents in one or more classifications will continue to be an important part of the search strategy when it is difficult to express search needs in textual terms.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-22 are rejected over the abbreviated term "KIAA". The abbreviation has not been explained either in the specification or in the claims. In absence of the fully explained abbreviation of the term "KIAA", it is not clear what is meant and encompassed by "KIAA markers" of the instant invention. The metes and bounds of the claims are vague and indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by An et al. (U.S. Patent 5,972,615) (October 26, 1999).

An et al. teaches a method of assessing whether a subject is afflicted prostate cancer (Abstract), the method comprising:

a) the level of expression of a marker in a sample from a subject, wherein the marker is selected from the group consisting of one or more KIAA markers (transglutaminase in this case) (Column 6, lines 1-10 and TABLE 4), and

b) the normal level of expression of the marker in a control sample, wherein a significant difference between the level of expression of the marker in the sample from the subject and the

normal level is an indication that the subject is afflicted with prostate cancer (TABLE 4 and Column 74, lines 15-25 and Claim 1).

An et al. teaches a method, wherein the marker corresponds to a transcribed polynucleotide or portion thereof, wherein the polynucleotide comprises the marker (TABLE 4 and Column 4, lines 41-54).

An et al. teaches a method, wherein the sample comprises cells obtained from the subject (Example 2).

An et al. teaches a method, wherein the cells are collected from the prostate gland (Example 2).

An et al. teaches a method, wherein the cells are collected from blood (Example 4).

An et al. teaches a method, wherein the level of expression of the marker in the sample differs from the normal level of expression of the marker in a subject not afflicted with prostate cancer by a factor of at least about 2 and 3 (Column 72, line 54 to Column 73, line 25).

An et al. teaches a method, wherein the marker is not significantly expressed in non-prostate cancer cells (Column 4, lines 15-40).

An et al. teaches a method, wherein the level of expression of the marker in the sample is assessed by detecting the presence in the sample of a protein corresponding to the marker (Column 4, lines 41-54).

An et al. teaches a method, wherein the presence of the protein is detected using a reagent (antibody or antibody derivative or fragment) which specifically binds with the protein (Column 7, lines 13-57 and Column 25, line 25 to Column 27, line 18).

An et al. teaches a method, wherein the level of expression of the marker in the sample is assessed by detecting the presence in the sample of a transcribed polynucleotide or portion thereof, wherein the transcribed polynucleotide comprises the marker (Example 4).

An et al. teaches a method, wherein the transcribed polynucleotide is an mRNA (Column 3, lines 56-67 and Column 6, lines 35-50 and Claim 13).

An et al. teaches a method, wherein the transcribed polynucleotide is a cDNA (Table 4).

An et al. teaches a method, wherein the step of detecting further comprises amplifying the transcribed polynucleotide (Column 5, lines 45-62 and Column 34, lines 56-65 and Example 4).

An et al. teaches a method, wherein the level of expression of the marker in the sample is assessed by detecting the presence in the sample of a transcribed polynucleotide which anneals with the marker or anneals with a portion of a polynucleotide, wherein the polynucleotide comprises the marker, under stringent hybridization conditions (Table 4 and Example 4 and Claims 10-11).

Regarding claim 17, KIAA markers (in absence of a specific definition in the specification or claims) are broadly interpreted as comprising transglutaminase, cytokeratin 15, and/or semenogelin II composition. An et al. teaches a method, further comprising comparing:

a) the level of expression in the sample of each of at least two KIAA markers independently (Claim 1), and

b) the normal level of expression of at least two KIAA markers in samples of the same type obtained from control subjects not afflicted prostate cancer (Claim 2),

wherein the level of expression of more than one of the markers is significantly altered, relative to the corresponding normal levels of expression of the markers, is an indication that the subject is afflicted prostate cancer (Claims 1-23).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 18-22 are rejected under 35 U.S.C. 103(a) over An et al. (U.S. Patent 5,972,615) (October 26, 1999) in view of Lal et al. (U.S. Patent 6,096,308) (August 1, 2000).

An et al teaches the method of claims 1-17 as described above including the transglutaminase (which is considered as KIAA 18) expression in prostate cancer.

An et al does not teach KIAA 96 expression (which is disclosed in the specification page 3, lines 12-13 as serine-threonine kinase) in prostate cancer.

Lal et al. teaches KIAA 96 expression (which is considered as serine-threonine kinase) in prostate cancer (Column 1, line 57 to Column 2, line 17).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the KIAA 96 expression (which is considered as serine-threonine kinase) in prostate cancer of Lal et al. in the method of An et al. since Lal et al. states "PKC is a synonym for a family of serine/threonine kinases that has been associated with signal transduction regulation, cell growth and differentiation but has recently been associated with the regulation of cell death as well (Column 1, line 67 to Column 2, line 4)". An ordinary practitioner would have been motivated to substitute and combine the KIAA 96 expression (which is considered as serine-threonine kinase) in prostate cancer of Lal et al. in the method of An et al. in order to achieve the express advantages, as noted by Lal et al., of the expression of a family of serine/threonine kinases that has been associated not only with signal transduction regulation, cell growth and differentiation but has recently been associated with the regulation of

cell death as well. The additional gene expression study would necessarily enhance and confirm the detection of prostate cell death caused by cancer.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located In Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published In the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti

Patent Examiner

Art Unit 1634,

September 17, 2003

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